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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,774	10/29/2001	Alessandra D'Azzo	2427/1F509-US1	9922
29311	7590	01/30/2004	EXAMINER	
DARBY & DARBY P.O. BOX 5257 NEW YORK, NY 10150-5257			FRONDA, CHRISTIAN L	
		ART UNIT	PAPER NUMBER	
		1652		

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,774	D'AZZO ET AL.	
	Examiner Christian L Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
 - 4a) Of the above claim(s) 1-8, 18 and 22-33 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 9-17 and 19-21 is/are rejected.
- 7) Claim(s) 9, 12, 20 and 21 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1/28/02,</u>
<u>2/5/02, 5/7/02, 12/23/02</u> | 6) <input type="checkbox"/> Other: ____ . |

Art Unit: 1652

DETAILED ACTION

Election/Restriction

1. Applicants' election with traverse of Group II, claims 9-17 and 19-21 and SEQ ID NO: 1, is acknowledged. Applicants' position is that Groups I, II, and VII contain unifying features which would require searches that are co-extensive. This is not found persuasive for reasons of record as supplemented below.

The protein of Group I and the nucleic acid of Group II are independent chemical entities. The protein of Group I is a polypeptide while the nucleic acid molecule of Group II is a polynucleotide. A search for the protein of Group I in the amino acid databases and a search of the nucleic acid of Group II in the nucleotide databases are different searches that are not co-extensive since different databases are searched.

The inventions of Groups II and VII are distinct since the nucleic acid product of Group II can be used in a process that is materially different from the process of Group VII such as using the nucleic acid in a recombinant process for making the Ozz protein.

Applicants' position regarding the election of one sequence is that a search for any one of SEQ ID NOs: 1-4 would require a search for all other sequences. This is not found persuasive for reasons of record and because each of the sequences are different in composition and nucleotide sequence which encode different proteins that have different amino acid sequences and compositions. While the MPEP suggests that 10 ESTs sequence may be examined, the claimed inventions are not ESTs but encompass patentably distinct sequences that encode different proteins and require different searches that are not co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-17 and 19-21 and SEQ ID NOs: 1 and 2 are under consideration in this Office Action.

Claim Objections

3. Claim 9 is objected to because the claim depends from nonelected claim 1. Applicants are required to cancel the claim or rewrite the claim in independent form. For examination purposes, it is assumed that claim 9 recite all the limitations of claim 1.

4. Claims 12, 20, and 21 are objected to because of the claims recited non-elected subject matter of the nucleotide sequence of SEQ ID NO: 3 . Applicants are required to cancel the claims or rewrite the claims to recite the elected nucleotide sequence of SEQ ID NO: 1.

Art Unit: 1652

Claim Rejections - 35 U.S.C. § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 9-17 and 19-21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequences of SEQ ID NO: 1, the deduced amino acid sequence of the Ozz protein encoded as SEQ ID NO: 2, and assigned the Ozz protein of SEQ ID NO: 2 as being involved in development and function of muscle which is a generic asserted utility. However, the specification does not disclose the **specific** function of the protein of SEQ ID NO: 2 or any activity assays to demonstrate that the protein has any biological activity.

The specification shows sequence alignments between the claimed invention and *Drosophila melanogaster* and *D. virilis* neuralized protein. However, homology is not a disclosure of how to use the protein or polynucleotide encoding the protein of SEQ ID NO: 2. The specification does not explicitly state that homology to a reference polypeptide known in the prior art is a disclosure that the claimed polypeptide has the properties and biological function of the reference polypeptide relied upon.

Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function associated with the protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 9-17 and 19-21 are rejected under 35 U.S.C. 112, first paragraph. Specifically,

Art Unit: 1652

since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 9-17 and 19-21 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

9. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to all possible polynucleotides of any biological function that hybridize to SEQ ID NO: 1. The specification, however, only provides the following representative species encompassed by these claims: a polynucleotide having a sequence of SEQ ID NO: 1 and a polynucleotide encoding SEQ ID NO: 2.

There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which no predictability of structure is apparent. The specification does not provide a written description of the entire genus of polynucleotides encompassed by the claim where the biological function of the members of the genus have yet to be discovered and described.

Given this lack of additional representative species and written description of the genus of polynucleotide encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is vague and indefinite because the meaning of the phrase "ten bases" is not known and because the specific hybridization conditions have not been recited. Furthermore, the specific nucleotide sequence/structure of the "PPCA exon Ia" is not known and not recited.

Art Unit: 1652

Claim Rejections - 35 U.S.C. § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (Oncogene. 1998 Feb 26;16(8):1009-19).

Since the specification states that the claimed protein named as "Ozz" is involved in development and function of muscle and has homology to Drosophila neuralized gene (*neu*) and that the claim does not recite or is limited to a specific nucleotide sequence (SEQ ID NO:); the claim is interpreted as encompassing any nucleic acid encoding any protein involved in development and function of muscle with homology with Drosophila *neu*.

Nakamura et al. teach a cDNA encoding a human homolog of the Drosophila neuralized gene (see entire publication, especially Figure 6). Thus, the reference teachings anticipate the claimed invention.

14. Claims 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Prinos et al. (Teratology, (1998 Feb) 57 (2) 108).

Since the specification states that the claimed protein named as "Ozz" is involved in development and function of muscle and has homology to Drosophila neuralized gene (*neu*) and that the claim does not recite or is limited to a specific nucleotide sequence (SEQ ID NO:); the claim is interpreted as encompassing any nucleic acid encoding any protein involved in development and function of muscle with homology with Drosophila *neu*.

Prinos et al. teach a cDNA for a mouse homolog of the Drosophila neuralized gene (see entire publication). Thus, the reference teachings anticipate the claimed invention.

15. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Accession AA800025).

Lee et al. teach a nucleic acid which is expected to hybridize to SEQ ID NO: 1 since no specific hybridization conditions have been recited (see enclosed alignment). Thus, the reference teaching anticipate the claimed invention.

Art Unit: 1652

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. The Examiner can be contacted Monday-Friday from 9AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571)272-0928. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



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